UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STEVEN STREZSAK, et al.,

Plaintiffs,

v.

ARDELYX INC., et al.,

Defendants.

Case No. 21-cv-05868-HSG

ORDER GRANTING MOTION TO DISMISS

Re: Dkt. No. 114

Pending before the Court is a motion to dismiss Lead Plaintiff's putative securities class action filed by Defendants Ardelyx Inc., Mike Raab, Justin Renz, and David Rosenbaum ("Defendants"). Dkt. No. 114. The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). For the reasons below, the Court **GRANTS** the motion to dismiss without leave to amend.

I. BACKGROUND

A. Factual Background

Defendant Ardelyx is a biopharmaceutical company that began developing tenapanor around 2009 as a treatment for irritable bowel syndrome. Dkt. No. 113 ¶ 26 (Third Amended Complaint ("TAC")). Several years later, Ardelyx pivoted to seeking FDA approval of tenapanor for the treatment of hyperphosphatemia, a condition resulting from high levels of phosphate in the blood. *Id.* ¶ 27.

Ardelyx conducted three clinical trials of tenapanor as a treatment for hyperphosphatemia (*i.e.*, excess serum phosphates) in patients with chronic kidney disease ("CKD") on dialysis using a "surrogate" endpoint – the level of serum phosphates measured in trial participants that could be attributed to the use of tenapanor – rather than a particular clinical outcome (*e.g.*, reduced morbidity or mortality). TAC ¶¶ 31–34.

In November 2017, the FDA provided Ardelyx with feedback on the protocol and statistical plan analysis for Ardelyx's upcoming second study. *Id.* ¶ 36. It advised Ardelyx in a letter that "[i]f the size of the effect of tenapanor on serum phosphorous [was] significantly smaller than the size of the effect of currently approved phosphate binders," Ardelyx would "need to address the clinical relevance of the effect size of [tenapanor] on serum phosphorus." *Id.* In response to Ardelyx's request for feedback concerning whether the results of its third study to be conducted in 2019 could support additional labeling claims, the FDA reiterated its previous advice in a December 2018 letter, stating that "[a]ssuming the trial is well-conducted and the size of the treatment effect is clinically relevant, we agree that the results could be described in labeling." *Id.* ¶ 37.

In March 2020, after the conclusion of the tenapanor clinical trials, senior Ardelyx officials attended a meeting with FDA personnel regarding the forthcoming tenapanor new drug application (NDA) ("March 2020 Meeting"). *Id.* ¶ 41. The FDA indicated that Ardelyx's NDA should address the clinical relevance of the magnitude of the treatment effect of tenapanor on serum phosphorus shown in the clinical trials because "while it had accepted serum phosphorus as a surrogate endpoint and basis for approval for products intended to treat hyperphosphatemia . . . a treatment effect of any magnitude is not considered sufficient to support approval." *Id.* ¶ 44. The FDA also noted that "it [was] interested in evidence supporting the conclusion that the magnitude of the treatment effect [of tenapanor was] clinically relevant, as opposed to 'expert opinion.'" *Id.* ¶¶ 44, 47. Plaintiff alleges that at least one Ardelyx official who attended the meeting interpreted the FDA's comments as indicating that the FDA would reject the NDA in the absence of data demonstrating that the smaller reduction in serum phosphorus achieved in the tenapanor trials benefited patients. *Id.* ¶ 48.

The results of the three clinical trials ultimtaely showed that tenapanor was less effective at reducing serum phosphorous than existing treatments. *Id.* ¶ 38. Plaintiff alleges that Defendants therefore falsely portrayed their interactions with the FDA as positive and approval of the tenapanor NDA as all but assured. *See id.* ¶¶ 55, 59, 64, 67, 69, 72, 74, 76, 78, 81, 83. For example, on May 7, 2020 and August 6, 2020, Ardelyx issued press releases characterizing the

data supporting the soon-to-be submitted tenapanor NDA as "strong" and "robust." *Id.* ¶¶ 55, 61. In November 2020, Defendant Rosenbaum stated at an investor conference that the tenapanor Phase 3 trials showed "that if you dose tenapanor [alone], you get a significant and clinically relevant phosphate lowering." *Id.* ¶¶ 66–68. During the same presentation, Defendants further assured investors that Ardelyx's "interactions [so] far with the [FDA] ha[d] gone exceedingly well." *Id.* ¶ 69.

On July 19, 2021, Ardelyx disclosed that the FDA had "identified deficiencies" in the NDA that precluded the application from moving forward. *Id.* ¶¶ 85–87. Ardelyx shares fell from their July 19 closing price of $7.70 per share to a July 20 closing price of only $2.01 per share, representing "a one-day drop of nearly 74%." *Id.* ¶ 87.

Plaintiff brings this putative class action on behalf of individuals who purchased or otherwise acquired Ardelyx securities between May 7, 2020 and July 19, 2021, inclusive ("Class Period"), and who were damaged as a result of Defendants' violations of the Exchange Act ("Class"). *Id.* ¶ 1.

B. Procedural Background

On March 18, 2024, the Court dismissed the Second Amended Complaint (Dkt. No. 97) on the ground that Plaintiff had not adequately alleged that Defendants misled investors about the tenapanor application. Dkt. No. 110 ("SAC Order"). Specifically, the Court held that Plaintiff did not sufficiently allege falsity under the PSLRA because he failed to allege that the FDA's statements convinced Defendants that the tenapanor review process was not actually proceeding in an ordinary manner, that the clinical data was not robust or clinically relevant, and that approval was thus in jeopardy. SAC Order at 9.

On April 14, 2024, Plaintiff filed the TAC (Dkt No. 113). Defendants moved to dismiss. Dkt. No. 114.

II. LEGAL STANDARD

C. Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A

defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when a plaintiff pleads "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, Courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

D. Heightened Pleading Standard

Section 10(b) of the Securities Exchange Act of 1934 provides that it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered . . . any manipulative or deceptive device or contrivance . . . ." 15 U.S.C. § 78j(b). Under this section, the SEC promulgated Rule 10b-5, which makes it unlawful, among other things, "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To prevail on a claim for violations of either Section 10(b) or Rule 10b-5, a plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). At the pleading stage, a complaint alleging claims under Section 10(b) and Rule 10b-5 must not only

meet the requirements of Federal Rule of Civil Procedure 8, but also satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Under Rule 9(b), claims alleging fraud are subject to a heightened pleading requirement, which requires that a party "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, all private securities fraud complaints are subject to the "more exacting pleading requirements" of the PSLRA, which require that the complaint plead with particularity both falsity and scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009).

III. REQUEST FOR JUDICIAL NOTICE

A. Incorporation by Reference

In the Ninth Circuit, incorporation by reference is a doctrine that "treats certain documents as though they are part of the complaint itself." *Khoja v. Orexigen Therapeutics*, 899 F.3d 988, 1002 (9th Cir. 2018). A document may be incorporated by reference into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). "Once a document is deemed incorporated by reference, the entire document is assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its contents." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir. 2014) (internal quotation marks and citation omitted). Although the truth of an incorporated document may not be considered *solely* to dispute *well-pled* facts, the Court need not accept as true conclusory allegations that are contradicted by documents referenced in the complaint. *See In re Eventbrite, Inc. Securities Litigation*, 2020 WL 2042078, at *7 (N.D. Cal. Apr. 28, 2020).

Defendants request that the Court incorporate Exhibits 1–4, 6, 10, and 12 into the TAC. The Court previously incorporated by reference into the SAC the documents now marked as Exhibits 1 through 4, 6, 10, and 12. SAC Order at 5. Plaintiff refers to and relies upon these same exhibits for the same purposes in the TAC. *See, e.g.*, TAC ¶¶ 51–53, 57–58, 62–63, 66–70, 71–73, 74–79, 80–82, 88–90, 91–93. The Court agrees that these documents either form the basis of

Plaintiff's claims or are referred to extensively in the TAC. *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). The Court grants the request to incorporate these documents by reference.

B. Judicial Notice

Under Federal Rule of Evidence 201, a court may take judicial notice of a fact "not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Accordingly, a court may take "judicial notice of matters of public record," but "cannot take judicial notice of disputed facts contained in such public records." *Khoja*, 899 F.3d at 999 (citation and quotations omitted). The Ninth Circuit has clarified that if a court takes judicial notice of a document, it must specify what facts it judicially noticed from the document. *Id.* at 999.

The Court has already taken judicial notice of the documents now marked as Exhibits 1–10 and 12. SAC Order at 5–7. The Court continues to take judicial notice of these documents.

Defendants additionally request that the Court take judicial notice of two new exhibits. Defendants first request the Court take notice of Exhibit 11, a quarterly financial report on Form 10-Q filed with the SEC. Ardelyx publicly filed this document with the SEC and it is available to the public through the SEC's website. These documents are not subject to reasonable dispute, and the "accuracy" of these publicly filed SEC documents "cannot reasonably be questioned." *Waterford Twp. Police v. Mattel, Inc.*, 321 F. Supp. 3d 1133, 1143 (C.D. Cal. 2018); *Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting that SEC filings are subject to judicial notice). Second, Defendants request that the Court take judicial notice of Exhibit 13, which depicts Ardelyx's historical stock price during the Class Period. Courts routinely take judicial notice of daily stock prices from credible sources, including Yahoo! Finance. *See, e.g., In re Nvidia Corp. Sec. Litig.*, 2010 WL 4117561, at *2, n. 3 (N.D. Cal. Oct. 19, 2010) (taking judicial notice of daily closing prices as reported by Yahoo! Finance); *Siemers v. Wells Fargo & Co.*, 2007 WL 1456047, at *2 (N.D. Cal. May 17, 2007) (taking judicial notice of Yahoo! Finance for company stock price)

Accordingly, the Court takes judicial notice of the documents described in this section for

the purpose of considering what was disclosed to the market. In doing so, the Court does not assume the truth of any of the facts asserted. *Wochos v. Tesla, Inc.*, 2018 WL 4076437, at *2 (N.D. Cal. Aug. 27, 2018.

IV. DISCUSSION

A. Section 10(b) and Rule 10b-5

Defendants contend that the statements challenged in the SAC are not materially false or misleading. "Falsity is alleged when a plaintiff points to [the] defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 at 1008. "In setting forth the reasons why they contend that each challenged statement is misleading, securities plaintiffs may rely either on an affirmative misrepresentation theory or an omission theory." *Wochos*, 985 F.3d at 1188 (citing 17 C.F.R. § 240.10b–5(b)). "Under Rule 10b–5, an affirmative misrepresentation is an 'untrue statement of a material fact.'" *Id.* "A statement is misleading if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017) (quotations and alterations omitted). "To be misleading, a statement must be 'capable of objective verification.'" *Id.* (internal citation removed). However, even "general statements of optimism, when taken in context," may be misleading "when those statements address specific aspects of a company's operation that the speaker knows to be performing poorly." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143 (9th Cir. 2017).

"Even if a statement is not false, it may be misleading if it omits material information." *Khoja*, 899 F.3d at 1008–09. "An omission is material when there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *Irving Firemen's Relief & Ret. Fund v. Uber Tech.*, 398 F. Supp. 3d 549, 555–56 (N.D. Cal. 2019) (citation omitted).

a. Previously Alleged Statements

With the exception of two new statements addressed further below, the TAC challenges the same statements as did the previous iteration of the complaint. Plaintiff claims that the Third

Amended Complaint now adequately pleads falsity as to these previously alleged statements, pointing to three new categories of allegations that support his theory of falsity.

First, Plaintiff alleges that "over a period of several years," the FDA "made clear to Ardelyx that approval of the tenapanor [NDA] depended on showing either a treatment effect for tenapanor comparable to existing phosphate binder therapies or evidence that tenapanor's smaller treatment effect was clinically relevant." Opp. at 11 (citing TAC ¶ 35–37, 41–47; Dkt No. 113-1 at 11.) Plaintiff also points to the November 2017 FDA letter, the December 2018 FDA letter, and the discussions during the March 2020 FDA meeting, all of which purportedly further demonstrate that the FDA suggested that approval would be difficult to reach given the results of the clinical trials. However, these supposedly new allegations were included in the prior complaint or were contained in documents that the Court incorporated into the SAC by reference. *See* SAC ¶ 44 (citing November 2017 FDA letter), *id.* ¶ 45 (citing December 2018 FDA letter), *id.* ¶¶ 7–10, 38, 40–42, 46–47 (discussing March 2020 FDA meeting), *see also* SAC Order at 5 (incorporating by reference FDA briefing document). Because Plaintiff fails to support this theory with newly alleged facts, the Court's previous holding remains undisturbed. Defendants' "years-long iterative dialogue with the FDA" did not render the opinion statements at issue false or misleading. CAC Order at 12.

Second, Plaintiff points to allegations that the trials demonstrated a treatment effect only one-third to one-half that of existing therapies. Dkt No. 116 at 12 ("Opp.") (citing TAC ¶¶ 38, 42). *Id.* Plaintiff argues that these facts give rise to the inference that Defendants possessed trial data that they knew would not be sufficient for FDA approval. *Id.* Again, the previous complaint referenced these allegations and the Court incorporated by reference documents that refer to this information. *See* SAC ¶¶ 59, 67, 73, 79, 84; *see also* SAC Order at 5 (incorporating by reference FDA briefing document). Because Plaintiff fails to support this theory with newly alleged facts, the Court again does not depart from its prior holding.

Third, Plaintiff points to the reaction of an unidentified "Ardelyx official attending the March 2020" FDA meeting. This official allegedly interpreted the FDA's guidance at the meeting to suggest that there was a "serious risk" that the FDA would deny the tenapanor application. *See*

Opp. at 12–13. Under the PSLRA, a complaint may rely on confidential witnesses in two situations. Where a complaint relies on both confidential witnesses and other factual information, such as documentary evidence, plaintiffs "'need not name their sources as long as the latter facts provide an adequate basis for believing that the defendants' statements were false.'" *Zucco Partners*, 552 F.3d at 995 (9th Cir. 2009) (internal citations and quotations removed). "Where as here, however, such additional evidence is absent, confidential witness statements may only be relied upon where the confidential witnesses are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Id.* (internal citations and quotations removed). Details such as the individual's job title, role, employment information, or any other information that might "make apparent [their] position within the defendant corporation" may suffice. *Id.* at 995–96. Plaintiff alleges none of these basic details that would allow the Court to infer any degree of reliability or personal knowledge as to this "official." *See Browning v. Amyris, Inc.*, 2014 WL 1285175, at *18 (N.D. Cal. Mar. 24, 2014 (rejecting reliance on a confidential witness the complaint described as a "senior scientist" because the complaint had not alleged when the person worked at the company, nor what the confidential witness's specific job responsibilities were, nor "who the [confidential witness] works with and what sources of information are available to him.") Because Plaintiff "fails to allege with particularity facts supporting its assumptions that the confidential witnesses were in a position to be personally knowledgeable of the information alleged," the allegations relating to the anonymous Ardelyx official do not support a finding that Plaintiff has adequately plead falsity. *Zucco Partners, LLC*, 552 F.3d at 996.[1]

b. Newly Alleged Statements

Plaintiff alleges two new statements in the TAC from Ardelyx's risk disclosures. Plaintiff first challenges the following disclosure in Ardelyx's March 2021 annual report:

[1] Plaintiff also argues that statements relating to "clinical relevance" constitute statements of fact rather than opinion, requiring a different analysis of falsity. The Court does not depart from its previous holding that the statement qualified as an opinion that was insufficiently alleged to be false or misleading. *See* SAC Order at 12 n.3.

> "The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our drug candidates for the proposed indication, the results my not be satisfactory to the FDA. Nonclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit, or prevent regulatory approval."

TAC ¶ 76. Plaintiff also challenges a disclosure from the same report noting that Tenapanor's "commercial success" depends on whether "tenapanor's safety and efficacy profile is satisfactory to the FDA and foreign regulatory authorities." *Id.* ¶ 78. Plaintiff contends that these warnings failed to inform investors that Ardelyx did not have the results necessary to gain FDA approval.

Notably, the Court previously found that these specific risk disclosures revealed the thrust of the allegedly omitted facts and thus undermined Plaintiff's theory of falsity. *See* SAC Order at 10. Given the dearth of new factual allegations supporting Plaintiff's theory of falsity, the Court's opinion is unchanged on this point. Moreover, to adequately challenge a risk disclosure, Plaintiff must allege particularized facts suggesting that the warned-of risks had already materialized at the time of the disclosure. *Veal v. Lendingclub Corp.*, 423 F. Supp. 3d 785, 809 (N.D. Cal. 2019) (dismissing on falsity grounds where plaintiff did not allege risk had materialized "at the time the risk disclosure statements were made"). Because the FDA had not communicated any determinations about the tenapanor application at the time of Defendants' risk warnings, Plaintiff fails to allege that the risk materialized.[2]

B. Section 20(a) Claim

Because Plaintiff does not adequately plead a Section 10(b) claim, his Section 20(a) claim fails. *See Lake v. Zogenix, Inc.*, 2020 WL 3820424, at *13 (N.D. Cal. Jan. 27, 2020).

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[2] Because Plaintiff fails to plead falsity, the Court need not analyze scienter or loss causation.

V. CONCLUSION

Plaintiff has failed to cure the defects in his complaint, and does not seek leave to amend. For the reasons stated above, the Court **GRANTS** the motion to dismiss without further leave to amend. The clerk is directed to enter judgment in favor of Defendants and close the file.

IT IS SO ORDERED.

Dated: 9/12/2024

HAYWOOD S. GILLIAM, JR.
United States District Judge